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10/663,286

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Mario Scurati

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TAMSEN VALOIR, PH.D.  
BAKER & MCKENZIE LLP  
PENNZOIL PLACE, SOUTH TOWER  
711 LOUISIANA, SUITE 3400  
HOUSTON, TX 77002-2746

EXAMINER

BOWERS, NATHAN ANDREW

ART UNIT

PAPER NUMBER

1797

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/663,286	<b>Applicant(s)</b> SCURATI ET AL.	
	<b>Examiner</b> NATHAN A. BOWERS	<b>Art Unit</b> 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 June 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-54 is/are pending in the application.
- 4a) Of the above claim(s) 32-44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-31 and 45-54 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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1) Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pourahmadi (US 20020055167) or Anderson (US 20010036672), and further in view of Levine (US 6031286).

With respect to claim 1, Pourahmadi discloses an integrated micro-device for analysis of a biological specimen comprising a support (Figure 16:165). The support includes an inlet port, a first tank (Figure 16:173) and a detection chamber (Figure 16:177). The first tank and detection chamber are fluidly connected via a plurality of buried channels formed inside the support. This is disclosed in paragraphs [0013], [0014], [0115], [0117], [0118] and [0199]-[0204]. Paragraph [0199] specifically states that the device further includes a printed circuit board (Figure 16:167) arranged next to the support. Paragraphs [0056] and [0064] indicate that the micro-device also comprises various sensors. The support and the sensors are operably coupled to the printed circuit board. Pourahmadi teaches in paragraph [0151] that the fluid channels in communication with reaction chambers have a width and diameter of at least 100 microns. Figures 19 and 20 of Pourahmadi disclose an embodiment in which a pre-treatment channel is situated above another channel, such that extracted compounds are moved from the pre-treatment channel to the lower channel through a filter (86).

Anderson discloses an integrated micro-device for analysis of a biological specimen comprising a support that includes a first tank (Figure 3:202) and a detection chamber (Figure 3:218). The first tank and detection chambers are fluidly connected by a plurality of pretreatment channels and buried channels. A plurality of additional chambers (Figure 3:206; 210; 214) are additionally provided in fluid communication with the first and detection chambers. This is disclosed in paragraphs [0009], [0037]-[0040] and [0080]. Paragraph [0088]

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indicates that detection equipment is provided at the detection chamber for determining the presence of various biological analytes. Anderson teaches in paragraph [0093] that fluid channels will typically have a width between 100 to 500 microns and a depth between 1 and 500 microns.

Pourahmadi and Anderson, however, do not clearly indicate that the channels are “buried channels.”

Levine discloses a method for creating buried microfluidic channels in a semiconductor wafer. This is disclosed in column 3, line 31 to column 4, line 54. Figures 3 and 4 show channels (35, 50) that are completely surrounded on all sides by the semiconductor substrate. Figure 4 further indicates that some channels (35) are formed underneath other channels (50).

Pourahmadi, Anderson, and Levine are analogous art because they are from the same field of endeavor regarding the use of microfluidic semiconductor wafers.

At the time of the invention, it would have been obvious to ensure that the microfluidic channels disclosed by Pourahmadi and Anderson are buried channels surrounded on all sides by the support substrate. Levine indicates that buried microchannels can be easily constructed in a semiconductor support using known etching and deposition techniques. Column 2, lines 8-17 indicates that buried microchannels are beneficial because they can be created in a cost effective manner. Buried microchannels can be formed in a variety of different geometries and shapes depending on the requirements of the current experiment.

With respect to claim 2, Pourahmadi discloses that a micropump is provided on the support for moving a specimen from the first tank to the detection chamber through the buried

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channel. Paragraphs [0065] and [0066] state that various pumps are utilized for moving fluids through the microfluidic system. Anderson also discloses that micropumps are provided on the support for moving a specimen from the first tank to the detection chamber through the buried channels. This is indicated in paragraph [0159].

With respect to claim 3, Pourahmadi discloses that a heater is provided on the disposable support. This is described in paragraph [0075]. Paragraphs [0021], [0064] and [0124]-[0126] disclose the use of software and control elements to regulate the functioning of the device. Anderson also discloses that a controllable heater is provided on the disposable support. This is described in paragraphs [0116] and [0117].

With respect to claims 4 and 8, Pourahmadi discloses the apparatus in claim 1 wherein electrodes are positioned on the support. This is disclosed in paragraphs [0135]-[0137]. Pourahmadi indicates that these electrodes, as well as additional micropumps, are used in moving specimens throughout the microfluidic system. In paragraph [0162], Anderson also discloses that electrodes are positioned on the support.

With respect to claim 5, Pourahmadi discloses that the support further comprises a second tank (Figure 16:201) fluidly coupled with a buried channel. It is apparent from Figures 2 and 16 that the support includes a plurality of fluid tanks. Anderson also discloses that the support further comprises a second tank (Figure 3:206) fluidly coupled with a buried channel. It is apparent from Figure 3 that the support includes a plurality of fluid tanks.

With respect to claims 6, 7 and 9, Pourahmadi discloses that the support comprises silicon. This is clearly indicated in paragraph [0097]. Silicon is considered to be a material characterized by a high thermal conductivity. Anderson also discloses that the support comprises silicon. This is clearly indicated in paragraph [0095]. Silicon is considered to be a material characterized by a high thermal conductivity.

2) Claims 10-14, 23/(10), 45-52 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pourahmadi (US 20020055167) or Anderson (US 20010036672), and further in view of Levine (US 6031286) and Ackley (US 6309602).

With respect to claims 10-14, 23/(10), 45 and 54, Pourahmadi discloses an integrated micro-device for analysis of a biological specimen comprising a support (Figure 16:165). The support includes an inlet port, a first tank (Figure 16:173) and a detection chamber (Figure 16:177). The first tank and detection chamber are fluidly connected via a plurality of buried channels formed inside the support. This is disclosed in paragraphs [0013], [0014], [0115], [0117], [0118] and [0199]-[0204]. Paragraph [0199] specifically states that the device further includes a printed circuit board (Figure 16:167) arranged next to the support. Paragraphs [0056] and [0064] indicate that the micro-device also comprises various sensors. The support and the sensors are operably coupled to the printed circuit board. Pourahmadi teaches in paragraph [0151] that the fluid channels in communication with reaction chambers have a width and diameter of at least 100 microns. Figures 19 and 20 of Pourahmadi disclose an embodiment in which a pre-treatment channel is situated above another channel, such that extracted compounds are moved from the pre-treatment channel to the lower channel through a filter (86).

Anderson discloses an integrated micro-device for analysis of a biological specimen comprising a support that includes a first tank (Figure 3:202) and a detection chamber (Figure 3:218). The first tank and detection chambers are fluidly connected by a plurality of pretreatment channels and buried channels. A plurality of additional chambers (Figure 3:206; 210; 214) are additionally provided in fluid communication with the first and detection chambers. This is disclosed in paragraphs [0009], [0037]-[0040] and [0080]. Paragraph [0088] indicates that detection equipment is provided at the detection chamber for determining the presence of various biological analytes. Anderson teaches in paragraph [0093] that fluid channels will typically have a width between 100 to 500 microns and a depth between 1 and 500 microns.

Pourahmadi and Anderson, however, do not clearly indicate that the channels are “buried channels.”

Levine discloses a method for creating buried microfluidic channels in a semiconductor wafer. This is disclosed in column 3, line 31 to column 4, line 54. Figures 3 and 4 show channels (35, 50) that are completely surrounded on all sides by the semiconductor substrate. Figure 4 further indicates that some channels (35) are formed underneath other channels (50).

Pourahmadi, Anderson, and Levine are analogous art because they are from the same field of endeavor regarding the use of microfluidic semiconductor wafers.

At the time of the invention, it would have been obvious to ensure that the microfluidic channels disclosed by Pourahmadi and Anderson are buried channels surrounded on all sides by the support substrate. Levine indicates that buried microchannels can be easily constructed in a semiconductor support using known etching and deposition techniques. Column 2, lines 8-17



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indicates that buried microchannels are beneficial because they can be created in a cost effective manner. Buried microchannels can be formed in a variety of different geometries and shapes depending on the requirements of the current experiment.

The combination of Pourahmadi/Anderson with Levine does not fully disclose Applicant's claimed invention because the combination does not indicate that a heater is arranged between the amplification channel and the pre-treatment channel.

Ackley discloses an integrated device for analysis of nucleic acid comprising a pre-treatment channel (Figure 4B:190) arranged below an amplification channel (Figure 4B:192). Ackley teaches in column 12, line 66 to column 13, line 19 that the sample solution is filtered and prepared in the pre-treatment channel and then sent to the amplification channel where PCR is utilized. It is apparent that the heater (206) of the amplification channel is positioned on the lower wall of the amplification channel so that it is disposed between the amplification channel and the pre-treatment channel.

Pourahmadi, Anderson and Ackley are analogous art because they are from the same field of endeavor regarding nucleic acid analysis devices.

At the time of the invention, it would have been obvious to dispose a heater between the amplification channel and the pre-treatment channel of the combination disclosed by Pourahmadi/Anderson and Levine. Levine already teaches that it is known in the art to arrange various channels one above another. Ackley is submitted as evidence that heaters positioned in a substrate material between a lower pre-treatment channel and an upper amplification channel are

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capable of effectively regulating the temperature within the upper amplification channel to complete PCR.

With respect to claims 46-49, Pourahmadi discloses that a heater is provided on the disposable support. This is described in paragraph [0075]. Paragraphs [0021], [0064] and [0124]-[0126] disclose the use of software and control elements to regulate the functioning of the device. Anderson also discloses that a controllable heater is provided on the disposable support. This is described in paragraphs [0116] and [0117].

With respect to claims 50-52, Pourahmadi discloses that the portable device includes a sample injection system that comprises a cap mechanism (Figure 16:185) through which samples are moved. Paragraphs [0021], [0064] disclose the use of software and control elements to regulate sample flow through a plurality of pretreatment and buried channels.

3) Claims 15-22, 23/(17,22), and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pourahmadi (US 20020055167) in view of Levine (US 6031286) and Ackley (US 6309602) as applied to claim 14, and further in view of Freeman (US 6653124).

With respect to claims 15, 16 and 18-21, Pourahmadi, Levine and Ackley disclose the apparatus set forth in claim 14 as set forth in the 35 U.S.C. 103 rejection above. Pourahmadi, however, does not expressly indicate that pre-treatment channels are formed above the support and confined by a containment structure and a protective cover.

Freeman discloses a microfluidic chip that comprises a plurality of detection chambers (Figure 1:12) and connecting fluid channels (Figure 1:14,16,18). Column 7, line 15 to column 9, line 64 indicates that the device is used for detecting nucleic acid hybridization reactions. Column 13, line 54 to column 14, line 8 indicate that the microfluidic structures are formed above a support (Figure 4:30), and are delimited laterally by containment structures (Figure 4:46,56) and on top by a protective plate (Figure 4:50) that covers the containment structures. Column 25, lines 25-33 and column 26, lines 21-41 indicate that the containment structures and covers are made from conductive polymeric materials, glass, circuit board, silicon, and other pertinent materials. The cover includes a transparent window to facilitate optical detection methods.

Pourahmadi and Freeman are analogous art because they are from the same field of endeavor regarding microfluidic detection devices.

At the time of the invention, it would have been obvious to provide pre-treatment channels in the apparatus disclosed by Pourahmadi that are formed above the support, rather than buried in the support. In column 13, line 54 to column 14, line 8, Freeman indicates that this type of construction is well known in the microfluidic art, and is particularly simple to create. The thickness of the containment structure can be regulated to quickly determine the height of the channels and chambers. Methods of sealing the support, containment structure, and cover together are well known in the art, and can be completed in an effective and precise manner.

With respect to claims 17 and 22, Pourahmadi, Levine, Ackley and Freeman disclose the apparatus set forth in claim 16 as set forth in the 35 U.S.C. 103 rejection above. In addition,

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Pourahmadi indicates in paragraphs [0135]-[0137] that electrodes are positioned in the flow channels in order to transport biomolecules using dielectrophoresis techniques. An electrostatic cage is formed since particles are allowed to move between areas characterized by a positive charge and areas characterized by a negative charge.

With respect to claims 23(17,22) and 24, Pourahmadi, Levine, Ackely and Freeman disclose the apparatus set forth in claims 17 and 22 as set forth in the 35 U.S.C. 103 rejection above. Pourahmadi additionally discloses in paragraphs [0065] and [0066] that various micropumps are utilized for moving fluids through the microfluidic system. Paragraph [0067] specifically discloses the use of vacuum pumps.

4) Claims 25-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pourahmadi (US 20020055167) in view of Levine (US 6031286), Ackley (US 6309602) and Freeman (US 6653124) as applied to claim 24, and further in view of Kaplan (US 6453928) and/or Webster (US 6521188).

Pourahmadi, Levine, Ackley and Freeman disclose the apparatus set forth in claim 24 as set forth in the 35 U.S.C. 103 rejection above, however do not provide specific information regarding the disclosed vacuum pumps.

Kaplan discloses a microfluidic pumping mechanism in which a plurality of chambers (Figure 5:132, 142, 152) are provided on a semiconductor support. The chambers are fluid tight, and are set at preset pressures. Column 1, line 63 to column 2, line 7, column 3, line 49 to column 4, line 29, and column 12, line 56 to column 14, line 6 indicate that fluids move between

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various chambers through suction channels. The fluid tight chambers are sealed by a diaphragm that is electrically openable. Electrodes (Figure 2:34) are provided creating holes in the diaphragms, and thereby initiating the pumping mechanism. This is disclosed in column 15, lines 15-25.

Webster discloses a similar system to that described by Kaplan. Webster discloses a plurality of pressurized chambers (Figure 1:13) that are connected via a suction channel (Figure 1:12). The pressurized chambers are sealed by a diaphragm that is opened by an electrode (Figure 1:15) near the inlet of each fluid chamber. This is disclosed in column 3, lines 37-67.

Pourahmadi, Kaplan and Webster are analogous art because they are from the same field of endeavor regarding microfluidic systems.

At the time of the invention, it would have been obvious to utilize the pumping mechanisms disclosed by Kaplan and Webster to move the fluids disclosed by Pourahmadi to and from the detection chamber. Kaplan and Webster each teach that their vacuum micropumping system is beneficial because it is less complicated, costly and cumbersome than many mechanically and valve based micropumps. The pressurized chambers disclosed by Kaplan and Webster can be easily incorporated into semiconductor material substrates, and can effectively be operated by a diaphragm and electrode combination. Limitations regarding the thickness of the diaphragm are not considered to patentable distinctions over the prior art because they represent result effective variables that are optimized through routine experimentation. See MPEP 2144.05.

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5) Claim 53 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pourahmadi (US 20020055167) in view of Levine (US 6031286) and Ackley (US 6309602) as applied to claim 52, and further in view of McDevitt (US 20030064422).

Pourahmadi, Levine and Ackley disclose the apparatus set forth in claim 52 as set forth in the 35 U.S.C. 103 rejection above, however do not expressly disclose that the detection chamber utilizes a CMOS detector.

McDevitt discloses a microfluidic chip that is capable of detecting nucleic acid analytes in a sample fluid. In paragraphs [0010], [0014] and [0503]-[0506], McDevitt teaches that target nucleic acids are hybridized to capture probes located in a detection chamber during the analysis of a sample solution. Paragraph [0561] states that CMOS detectors are utilized to determine the presence of analytes.

Pourahmadi and McDevitt are analogous art because they are from the same field of endeavor regarding microfluidic biochemical detection apparatuses.

At the time of the invention, it would have been obvious to provide the detection chamber disclosed by Pourahmadi with a CMOS detector. McDevitt discloses in paragraph [0561] that CMOS detectors are advantageous over other traditional detection devices because they can easily be fit within the casing of a portable sensor array system. McDevitt also indicates that CMOS detectors are low in cost and power consumption. Furthermore, CMOS detectors would have been beneficial to implement because they allow one to place sensing elements and microelectronics on a single integrated chip.

***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6) Claims 1, 3, 4, 6 and 7 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 and 10-14 of copending Application No. 09/874382. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications claim a micro-device comprising a support, buried channels, and a detection chamber. The instant application is generic to Application No. 09/874382 in the sense that the claims of Application No. 09/874382 disclose the support to specifically be a semiconductor material body, whereas the instant application does not make this requirement in the independent claims. Furthermore, the claims of Application No. 09/874382 specifically disclose the use of sensing electrodes, rather than broadly claiming a standard detection chamber.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

7) Claims 1, 3-7 and 10-13 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 16-20 of copending Application No. 11/017272. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications claim a micro-device comprising a support, buried channels, and a detection chamber. The instant application is generic to Application No. 11/017272 in the sense that the claims of Application No. 11/017272 disclose the support to specifically be a semiconductor material body whereas the instant application does not make this requirement in the independent claims. Furthermore, the claims of Application No. 11/017272 specifically disclose the use of a nucleic acid detection chamber comprising an array of probes, rather than broadly claiming a standard detection chamber. Application No. 11/017272 additionally discloses multiple processing chambers fluidly linked to inlets, outlets, and the detection chamber through a microfluidic circuit.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

8) Claims 1, 6 and 7 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 and 34 of copending Application No. 11/009171. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications claim a micro-device comprising a support, buried



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channels, and a detection chamber. The instant application is generic to Application No.

11/009171 in the sense that the claims of Application No. 11/009171 disclose the support to specifically be a monolithic body made from semiconductor material. Furthermore, the claims of Application No. 11/009171 specifically disclose the use of a detection area that is observed through an opening formed in the body, rather than broadly claiming a standard detection chamber.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

9) Claims 1-3, 5-7, 10-14 and 45-49 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 9, 10, 13-15 17, 19 and 20 of copending Application No. 11/092415. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications claim a micro-device comprising a support, buried channels, a detection chamber, and a printed circuit board. The instant application is generic to Application No. 11/092415 in the sense that the claims of Application No. 11/092415 disclose additional limitations regarding the structure of the temperature control device. The claims of Application No. 11/092415 additionally disclose a heater, micropump, the use of semiconductor materials, and that the sample to be analyzed comprises nucleic acids.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Response to Arguments***

The declaration filed on 16 June 2008 under 37 CFR 1.132 has been considered but is ineffective to overcome the combination of Pourahmadi, Anderson and Levine references as applied to claims 1-9.

The declaration offers strictly opinion testimony and is largely void of factual evidence. Inventor Scurati's theory regarding the likelihood of success of constructing buried channels of larger dimensions (200 microns by 150 microns) using the teachings of Levine have been considered, but ultimately they are not persuasive because they are not supported by objective experimental data. In assessing the probative value of an expert opinion, the examiner must consider the nature of the matter sought to be established, the strength of any opposing evidence, interest of the expert in the outcome of the case, and the presence or absence of factual support for the expert's opinion. MPEP 716(c). In the instant case, the submitted opinions are not, as previously noted, supported by experimental data. While there is no additional evidence on the record that directly opposes declarant, it must be noted that the Levine reference does not suggest that the disclosed micropipes are restricted to a narrow range of heights and widths.

Applicant's arguments filed 16 June 2008 with respect to the rejections of claims 10-31 and 45-54 involving the combination of either Pourahmadi or Anderson with Levine have been fully considered and are persuasive. Therefore, these rejections have been withdrawn. However, upon further consideration, a new ground of rejection is made in view of the combination of Pourahmadi or Anderson with Levine and Ackley.

Ackley indicates that it is known in the art to arrange an amplification channel directly above a pre-treatment channel in a microfluidic nucleic acid analysis device. Ackley further discloses that heaters are positioned between the amplification channel and the pre-treatment channel.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan A. Bowers whose telephone number is (571) 272-8613. The examiner can normally be reached on Monday-Friday 8 AM to 5 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/William H. Beisner/  
Primary Examiner, Art Unit 1797

/Nathan A Bowers/  
Examiner, Art Unit 1797